Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

3rd July 2023

Dear [redacted]

FOI 23/407

Thank you for your email dated 5 June 2023 in response to FOI 23/107, requesting additional information for the following:

- Within the breakdown of ADRs, show the breakdown of the number of fatalities
- Adverse reactions for the COVID vaccines and other medications for each of the members of the CCG
- Indicate if any victims have applied for compensation under the Government scheme
- Provide estimates or statements which explain what percentages are reported vs percentage unreported for deaths or in general

In our previous response (FOI 23/107) we confirmed that the MHRA has received a total of 8953 spontaneous suspected ADR reports for the NHS Buckinghamshire CCG area up to and including 23 February 2023, and of these 104 suspected ADR reports reported a fatal outcome.
Table 3 has been updated to include a breakdown of the fatal reports within each System Organ Class (SOC).

The Buckinghamshire CCG is a 50-member group of GP practices and their associated branches. In line with our duty of confidentiality to patient and reporters we only provide these data at CCG level. CCG data is derived based on postcode; however more granular data cannot be provided as GP data is not routinely requested for every report.

In response to your question on the Government compensation scheme; the NHS Business Services Authority (NHSBSA) operates the Vaccine Damage Payments Scheme (VDPS) on behalf of the Department of Health and Social Care (DHSC). The MHRA and the Yellow Card scheme has no relationship to the VDPS, and we do not hold data pertaining to this.

The reporting rate for spontaneous adverse drug reactions can depend on a multitude of factors. There is an unknown and variable level of under-reporting of adverse drug reactions (ADRs) from both healthcare professionals and patients, as there is with all spontaneous ADR reporting systems. Despite this, the Yellow Card Scheme is vital in helping the MHRA monitor the safety of all healthcare products in the UK to ensure they are safe for patients and those that use them.

The reporting rate is variable and will be influenced by public awareness and seriousness of the event. For COVID-19 vaccines, we worked to ensure there was high public awareness of the Yellow Card scheme and encouragement of reporting of all events on materials provided to the public prior to

vaccination. We have in place a proactive strategy to monitor the safety of the COVID-19 vaccines. Additionally, we take into account the variable levels of reporting across all medicines and vaccines as part of our monitoring procedures using statistical techniques and other data sources.

I hope the information provided is helpful, but if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,
Safety and Surveillance

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office
Wycliffe House
Water Lane
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SK9 5AF